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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/660,069 | 09/11/2003 | Ronald L. Hayes | UF-530XT | 7655 |

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| EXAMINER | |
|---|---|
| WEGERT, SANDRA L | |
| **ART UNIT** | **PAPER NUMBER** |
| 1647 | |

DATE MAILED: 11/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/660,069 | HAYES ET AL. | |
| | Examiner | Art Unit | |
| | Sandra Wegert | 1647 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *19 July 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-37* is/are pending in the application.

4a) Of the above claim(s) *1-20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21-37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *11 September 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/27/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## Detailed Action

***Status of Application, Amendments, and/or Claims***

The Information Disclosure Statement, sent 27 April 2004, has been entered into the record. Applicants' election of Invention II (Claims 21-37) in the paper of 19 July 2006 has been entered. Applicants traversed the restriction, arguing that it would not be an undue burden to search Invention I with Invention II. However, the search required to examine methods of using the spectrin breakdown products *along with* the compounds themselves would be burdensome. Applicants are reminded that, upon allowance, the first enabled method of using the claimed compound will be rejoined to the examined Invention, if it too is free of the art. However, until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims should be maintained (*In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b), 1184 O.G. 86 March 26, 1996). Claims 1-20 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected Invention, there being no allowable generic or linking claim.

Claims 21-37 are under examination in the Instant Application.

## Informalities

### *Specification*

The disclosure is objected to because of the following informalities:

***Title***

The title of the invention is not descriptive. A new title is suggested that is clearly indicative of the invention to which the claims are directed. It is suggested that the new title contain the word "spectrin," for example.

Appropriate correction of the title is recommended but not required.

***Continuity***

Applicants have not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows: The reference to the prior provisional application in the first paragraph of the Specification is listed with the wrong filing date. Applicants may amend the Specification directly to correct the error, or submit an Application Data Sheet (37 CFR 1.76).

Appropriate correction is required.

## Claim Rejections/Objections

***Claim Objections***

Claims 22 and 31 are objected to because they do not end in a period (see MPEP § 608.01(m)).

Claims 25 and 34 are objected to for depending from a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Appropriate correction is required.

***35 USC § 112, first paragraph – Written Description.***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> **The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.**

Claims 21-24, 26-33 and 35-37 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

The claims are directed to a mixture comprising a biological sample and an *agent* that specifically binds one or several spectrin breakdown products (SBDP). Dependent claims recite the specific spectrin breakdown products as well as the proteases that cleave spectrin. Further claim limitations are presented to detectable labels conjugated to the specific binding *agents* and to the mixture on an immobilized substrate.

The specification teaches use of Western blots to detect spectrin breakdown products produced by cerebral ischemia in rats and head-trauma in humans. Several specific antibodies are used to identify the breakdown products from alpha-II spectrin, as well as to identify the proteases responsible for generating the specific spectrin breakdown products. However, the specification does not teach functional or structural characteristics of any other *agents* that specifically bind the spectrin breakdown products, or that might be expected to specifically bind the SBDP's. The description of one kind of *agent* that binds SBDP's specifically, and are easy to generate, is not adequate written description of an entire genus of functionally-equivalent *agents* that bind SBDP's specifically.

To provide evidence of enablement of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, the only factor present in the claims is a recitation that the *agent* "specifically binds" one of the disclosed spectrin-breakdown products. There is not even identification of the class of compounds that would have such characteristics.

Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus.

*Vas-Cath Inc. v. Mahurkar*, 19USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed"* (See page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed" (See *Vas-Cath* at page 1116).

With the exception of the antibodies referred to above, the skilled artisan cannot envision the detailed chemical structure of all claimed agents that specifically bind SBDP's, and therefore, would not know how to use them. Conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of making or use. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of making. The product *itself* is required. See *Fiers v. Revel*, 25

USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Therefore, only antibodies that specifically bind SBDP's, but not the full breadth of the claims, meet the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

**Reference of Interest:**

The claimed invention in US Patent 5,118,606 (submitted with the Applicants' IDS of 27 April 2004) can be considered prior art over the non-elected invention of the instant Application.

*Claim rejections- 35 USC §103, obviousness*

**The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:**

> **(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.**

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out

the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 21-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lynch, et al (US Patent, 5,118, 606, submitted with the Applicants' IDS of 27 April 2004). Lynch, et al, teach the methods recited in instant claims 1-20. They also recite using the methods to detect spectrin breakdown products. They recite methods for detecting spectrin breakdown products in tissues in contact with the nervous system and recite the involvement of caspases. They also recite several methods of detecting spectrin breakdown products on immobilized substrates. They do not teach the specific spectrin breakdown products, as recited in Claims 21-37 of the instant Application.

However, if the method of using products is anticipated in the art, the composition for performing the method is obvious. In fact, in Lynch, et al, the conclude their discussion (Col. 12) by discussing the antibodies they had synthesized against the naturally occurring spectrin breakdown products, which were then used for the claimed method. These spectrin breakdown products are no doubt one and the same as those recited in claims 21-37 of the instant invention.

**Claim Rejections - 35 USC § 112, second paragraph, indefiniteness.**

The following is a quotation of the second paragraph of 35 U.S.C. 112:

**The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter that the applicant regards as his invention.**

Claims 23 and 32 are rejected under 35 U.S.C. 112, -second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims recite an agent that "does not" specifically bind at least one of [SBDP's]. However, one skilled in the art cannot determine the metes and bounds of the claimed invention because the invention is comprised of antibodies that have been shown to specifically bind the recited SBDP's. Agents that do not bind at least one of the specific SBDP's would include all or most known chemical products *except* specific antibodies. If the claims are intended to embrace antibodies that can discriminate *among* the spectrin breakdown products, it should state that explicitly.

**Conclusion**: Claims 21-37 are rejected for the reasons recited above.

**Advisory information**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Wegert whose telephone number is (571) 272-0895. The examiner can normally be reached Monday - Friday from 9:00 AM to 5:00 PM (Eastern Time). If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Brenda Brumback, can be reached at (571) 272-0961.

The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SLW
31 October 2006

Eileen B O'Hara

EILEEN B. O'HARA
PRIMARY EXAMINER